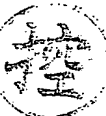


09/831901  
531 R&D PCT/PTC 25 MAY 2001



CORRECTION



To : Commissioner of the Patent Office

1 Identification of the International Application

PCT/JP99/06602

2 Applicant

Name : TAKADA Kanji

Address : 618-2, Gokoumachidori Gojoagaru Azuchi-cho, Shimogyo-ku,  
Kyoto-shi, Kyoto 600-8040 JAPAN

Country of nationality : JAPAN

Country of residence : JAPAN

3 Agent

Name : IMAMURA Masazumi

Signature

Address : 5th Floor, KRF Bldg., 5-5, Kyobashi 1-chome, Chuo-ku,  
Tokyo 104-0031 JAPAN

4 Date of Invitation 07. 12. 99

5 Item to be Corrected

Box No.IX SIGNATURE OF APPLICANT OR AGENT of the Request

6 Subject Matter of Correction As per the attached sheets

7 List of Attached Documents


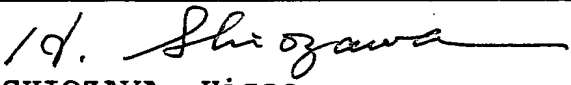
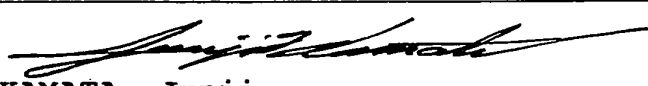
Request page no.3

One copy

## PCT REQUEST

99355M

Original (for SUBMISSION) - printed on 26.11.1999 11:08:26 AM

VI-3	<b>Priority document request</b> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1, VI-2	
VII-1	<b>International Searching Authority Chosen</b>	European Patent Office (EPO) (ISA/EP)	
VIII	<b>Check list</b>	number of sheets	electronic file(s) attached
VIII-1	Request	4	-
VIII-2	Description	39	-
VIII-3	Claims	3	-
VIII-4	Abstract	1	99355m.txt
VIII-5	Drawings	5	-
VIII-7	TOTAL	52	
	<b>Accompanying items</b>	paper document(s) attached	electronic file(s) attached
VIII-8	Fee calculation sheet	✓	-
VIII-9	Separate signed power of attorney	✓	-
VIII-16	PCT-EASY diskette	-	diskette
VIII-17	Other (specified):	patent revenue stamps	-
VIII-17	Other (specified):	certificate of payment of fee	-
VIII-18	Figure of the drawings which should accompany the abstract		
VIII-19	Language of filing of the international application	English	
IX-1	Signature of applicant or agent		
IX-1-1	Name (LAST, First)	IMAMURA, Masazumi	
IX-2	Signature of applicant or agent		
IX-2-1	Name (LAST, First)	SHIOZAWA, Hisao	
IX-3	Signature of applicant or agent		
IX-3-1	Name (LAST, First)	KAMATA, Junji	

## FOR RECEIVING OFFICE USE ONLY

10-1	Date of actual receipt of the purported international application	
10-2	Drawings:	
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	



## PCT REQUEST

Original (for SUBMISSION) - printed on 26.11.1999 11:08:26 AM

99355M

0	For receiving Office use only	
0-1	International Application No.	
0-2	International Filing Date	
0-3	Name of receiving Office and "PCT International Application"	
0-4	Form - PCT/RO/101 PCT Request Prepared using	PCT-EASY Version 2.90 (updated 15.10.1999)
0-5	Petition The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	Receiving Office (specified by the applicant)	Japanese Patent Office (RO/JP)
0-7	Applicant's or agent's file reference	99355M
I	Title of invention	An Oral Formulation for Gastrointestinal Drug Delivery
II	Applicant	
II-1	This person is:	applicant and inventor
II-2	Applicant for	all designated States
II-4	Name (LAST, First)	TAKADA, Kanji
II-5	Address:	618-2, Gokoumachidori Gojoagaru Azuchi-cho, Shimogyo-ku Kyoto-shi, Kyoto 600-8040 Japan
II-6	State of nationality	JP
II-7	State of residence	JP
IV-1	Agent or common representative; or address for correspondence The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	agent
IV-1-1	Name (LAST, First)	IMAMURA, Masazumi
IV-1-2	Address:	5th Floor, KRF Bldg., 5-5, Kyobashi 1-chome Chuo-ku, Tokyo 104-0031 Japan
IV-1-3	Telephone No.	03-3271-1331
IV-1-4	Facsimile No.	03-3271-1410
IV-2	Additional agent(s)	additional agent(s) with same address as first named agent
IV-2-1	Name(s)	SHIOZAWA, Hisao; KAMATA, Junji



## PCT REQUEST

99355M

Original (for SUBMISSION) - printed on 26.11.1999 11:08:26 AM

V V-1	<b>Designation of States</b>	
	Regional Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	<p>AP: GH GM KE LS MW SD SL SZ TZ UG ZW and any other State which is a Contracting State of the Harare Protocol and of the PCT</p> <p>EA: AM AZ BY KG KZ MD RU TJ TM and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT</p> <p>EP: AT BE CH&amp;LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE and any other State which is a Contracting State of the European Patent Convention and of the PCT</p> <p>OA: BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG and any other State which is a member State of OAPI and a Contracting State of the PCT</p>
V-2	National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned)	<p>AE AL AM AT AU AZ BA BB BG BR BY CA CH&amp;LI CN CR CU CZ DE DK DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW</p>
V-5	<b>Precautionary Designation Statement</b> In addition to the designations made under items V-1, V-2 and V-3, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except any designation(s) of the State(s) indicated under item V-6 below. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit.	
V-6	<b>Exclusion(s) from precautionary designations</b>	NONE
VI-1 VI-1-1 VI-1-2 VI-1-3	<b>Priority claim of earlier national application</b> Filing date Number Country	27 November 1998 (27.11.1998) Patent Application 10-353966 JP
VI-2 VI-2-1 VI-2-2 VI-2-3	<b>Priority claim of earlier national application</b> Filing date Number Country	21 September 1999 (21.09.1999) Patent Application 11-266433 JP

## PCT REQUEST

99355M

Original (for SUBMISSION) - printed on 26.11.1999 11:08:26 AM

VI-3	<b>Priority document request</b> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1, VI-2	
VII-1	<b>International Searching Authority Chosen</b>	European Patent Office (EPO) (ISA/EP)	
VIII	<b>Check list</b>	number of sheets	electronic file(s) attached
VIII-1	Request	4	-
VIII-2	Description	39	-
VIII-3	Claims	3	-
VIII-4	Abstract	1	99355m.txt
VIII-5	Drawings	5	-
VIII-7	TOTAL	52	
	<b>Accompanying items</b>	paper document(s) attached	electronic file(s) attached
VIII-8	Fee calculation sheet	✓	-
VIII-9	Separate signed power of attorney	✓	-
VIII-16	PCT-EASY diskette	-	diskette
VIII-17	Other (specified):	patent revenue stamps	-
VIII-17	Other (specified):	certificate of payment of fee	-
VIII-18	Figure of the drawings which should accompany the abstract		
VIII-19	Language of filing of the international application	English	
IX-1	<b>Signature of applicant or agent</b>		
IX-1-1	Name (LAST, First)	IMAMURA, Masazumi	
IX-2	<b>Signature of applicant or agent</b>		
IX-2-1	Name (LAST, First)	SHIOZAWA, Hisao	
IX-3	<b>Signature of applicant or agent</b>		
IX-3-1	Name (LAST, First)	KAMATA, Junji	

## FOR RECEIVING OFFICE USE ONLY

10-1	<b>Date of actual receipt of the purported international application</b>	
10-2	<b>Drawings:</b>	
10-2-1	Received	
10-2-2	Not received	
10-3	<b>Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application</b>	

## PCT REQUEST

99355M

Original (for SUBMISSION) - printed on 26.11.1999 11:08:26 AM

10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/EP
10-6	Transmittal of search copy delayed until search fee is paid	

## FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	
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## PCT (ANNEX - FEE CALCULATION SHEET)

99355M

Original (for SUBMISSION) - printed on 26.11.1999 11:08:26 AM

(This sheet is not part of and does not count as a sheet of the international application)

<b>0</b>	<b>For receiving Office use only</b>	
0-1	International Application No.	
0-2	Date stamp of the receiving Office	
0-4	<b>Form - PCT/RO/101 (Annex)</b>	
0-4-1	PCT Fee Calculation Sheet Prepared using	<b>PCT-EASY Version 2.90 (updated 15.10.1999)</b>
0-9	Applicant's or agent's file reference	<b>99355M</b>
2	Applicant	<b>TAKADA, Kanji</b>
12	<b>Calculation of prescribed fees</b>	
12-1	Transmittal fee T	⇒ 18,000
12-2	Search fee S	⇒ 120,000
12-3	International fee	
	Basic fee (first 30 sheets) b1	54,800
12-4	Remaining sheets	22
12-5	Additional amount (X) b2	1,300
12-6	Total additional amount	28,600
12-7	b1 + b2 = B	83,400
12-8	Designation fees	
	Number of designations contained in international application	82
12-9	Number of designation fees payable (maximum 10)	10
12-10	Amount of designation fee (X)	12,600
12-11	Total designation fees D	126,000
12-12	PCT-EASY fee reduction R	-16,900
12-13	Total International fee (B+D-R) I	⇒ 192,500
12-14	Fee for priority document	
	Number of priority documents requested	2
12-15	Fee per document (X)	1,500
12-16	Total priority document fee P	⇒ 3,000
12-17	<b>TOTAL FEES PAYABLE (T+S+I+P)</b>	⇒ <b>333,500</b>
12-19	Mode of payment	Transmittal fee: revenue stamps Search fee: revenue stamps International fee: bank draft Priority document fee: revenue stamps

## VALIDATION LOG AND REMARKS

13-1-1	Applicant remarks Names	9621 PATENT ATTORNEY IMAMURA Masazumi
13-1-2	Applicant remarks Names	9263 PATENT ATTORNEY SHIOZAWA Hisao

## PCT (ANNEX - FEE CALCULATION SHEET)

99355M

Original (for SUBMISSION) - printed on 26.11.1999 11:08:26 AM

13-1-3	Applicant remarks Names	9584 PATENT ATTORNEY KAMATA Junji
13-2-1	Validation messages Request	Green? The title of the invention should preferably be entered in capital letters. Please verify.
13-2-2	Validation messages States	Green? More designations could be made. Please verify.
13-2-3	Validation messages Names	Green? Applicant 1.:Telephone No. missing
		Green? Applicant 1.:Facsimile No. missing
13-2-6	Validation messages Contents	Green? Figure of the drawings which should accompany the abstract not specified. Please verify.
13-2-9	Validation messages Annotate	Yellow! All indications that can be made on the Request form are specifically provided for by the software. Please confirm validity of additional indication.
13-2-10	Validation messages For receiving Office/International Bureau use only	Green? Verify electronic data for consistency against printed form.

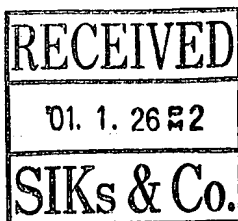


# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

IMAMURA, Masazumi  
5th Floor, KRF Bldg., 5-5,  
Kyobashi 1-chome  
Chuo-ku, Tokyo 104-0031  
JAPON



## PCT

### NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

23.01.2001

Applicant's or agent's file reference  
99355M

#### IMPORTANT NOTIFICATION

International application No.  
PCT/JP99/06602

International filing date (day/month/year)  
26/11/1999

Priority date (day/month/year)  
27/11/1998

Applicant  
TAKADA Kanji et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

#### 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

 European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Baillou, V

Tel. +49 89 2399-8236



# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 99355M	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP99/06602	International filing date (day/month/year) 26/11/1999	Priority date (day/month/year) 27/11/1998
International Patent Classification (IPC) or national classification and IPC A61K9/20		
Applicant TAKADA Kanji et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  07/02/2000	Date of completion of this report  23.01.2001
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Hedegaard, A  Telephone No. +49 89 2399 8644  

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP99/06602

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

### Description, pages:

1-39 as originally filed

### Claims, No.:

1-13 as originally filed

### Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/JP99/06602

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-13
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-13
Industrial applicability (IA)	Yes:	Claims 1-13
	No:	Claims

2. Citations and explanations  
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**Re Section V**

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-4 765 983

D2: WO-A-98 24412

D1 discloses (see Fig. 1, col. 2, lines 58-68 and column 5, lines 64-68) an oral formulation comprising an adhesion site-controlling layer (3), a drug-carrying layer (2) containing a drug and a water-soluble polymer (e.g. an adhesive such as polyvinyl alcohol, sodium polyacrylate and methylcellulose) and a protecting layer (1), wherein the drug-carrying layer exists between the protecting layer and the adhesion site-controlling layer.

D2 discloses (see example 1) enteric coated particles, where the particles comprise a drug and a mucoadhesive and the enteric coating comprises e.g. Eudragit S100 or Eudragit L100. According to page 6, line 7 of D2 the particles can be placed into capsules.

Hence, the particle can be characterized as the drug-carrying layer, the enteric coating as the adhesion site-controlling layer and the capsule as the protecting layer (in accordance with present claim 1).

2. The subject-matter of claim 1 is not novel (Art. 33(2) PCT) over D1 and D2, each document taken separately (see above under item 1).
3. In any claims amended to overcome the novelty objection it will be necessary that said claims satisfy the requirements of inventive step (Art. 33(3) PCT). With regard to the assessment of inventive step in particular the document D2 appears relevant since concerned with oral formulations for gastrointestinal drug delivery.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

---

International application No. PCT/JP99/06602

4. A positive international preliminary report for the subject-matter of the dependent claims 2-13 can only be established when they refer to independent claims which meet the requirements of the PCT.

**Re Section VII**

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

124 T 10005

PATENT COOPERATION TREATY

PCT

REC'D 25 JAN 2001

WIPO

PCT

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 99355M	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP99/06602	International filing date (day/month/year) 26/11/1999	Priority date (day/month/year) 27/11/1998
International Patent Classification (IPC) or national classification and IPC A61K9/20		
Applicant TAKADA Kanji et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  07/02/2000	Date of completion of this report  23.01.2001
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Hedegaard, A  Telephone No. +49 89 2399 8644



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP99/06602

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

### Description, pages:

1-39 as originally filed

### Claims, No.:

1-13 as originally filed

### Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
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- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/JP99/06602

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1-13
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-13
Industrial applicability (IA)	Yes:	Claims 1-13
	No:	Claims

2. Citations and explanations  
**see separate sheet**

## VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**R S ction V**

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-4 765 983

D2: WO-A-98 24412

D1 discloses (see Fig. 1, col. 2, lines 58-68 and column 5, lines 64-68) an oral formulation comprising an adhesion site-controlling layer (3), a drug-carrying layer (2) containing a drug and a water-soluble polymer (e.g. an adhesive such as polyvinyl alcohol, sodium polyacrylate and methylcellulose) and a protecting layer (1), wherein the drug-carrying layer exists between the protecting layer and the adhesion site-controlling layer.

D2 discloses (see example 1) enteric coated particles, where the particles comprise a drug and a mucoadhesive and the enteric coating comprises e.g. Eudragit S100 or Eudragit L100. According to page 6, line 7 of D2 the particles can be placed into capsules.

Hence, the particle can be characterized as the drug-carrying layer, the enteric coating as the adhesion site-controlling layer and the capsule as the protecting layer (in accordance with present claim 1).

2. The subject-matter of claim 1 is not novel (Art. 33(2) PCT) over D1 and D2, each document taken separately (see above under item 1).
3. In any claims amended to overcome the novelty objection it will be necessary that said claims satisfy the requirements of inventive step (Art. 33(3) PCT). With regard to the assessment of inventive step in particular the document D2 appears relevant since concerned with oral formulations for gastrointestinal drug delivery.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

---

International application No. PCT/JP99/06602

4. A positive international preliminary report for the subject-matter of the dependent claims 2-13 can only be established when they refer to independent claims which meet the requirements of the PCT.

**Re Section VII**

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

# PATENT COOPERATION TREATY



From the:  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

## PCT

### WRITTEN OPINION

(PCT Rule 66)

To:

IMAMURA, Masazumi  
5th Floor, KRF Bldg., 5-5,  
Kyobashi 1-chome  
Chuo-ku, Tokyo 104-0031  
JAPON

Date of mailing (day/month/year)	31.07.2000
-------------------------------------	------------

Applicant's or agent's file reference  
99355M

<b>REPLY DUE</b>	<b>within 3 month(s)</b> from the above date of mailing
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International application No.  
PCT/JP99/06602

International filing date (day/month/year)  
26/11/1999

Priority date (day/month/year)  
27/11/1998

International Patent Classification (IPC) or both national classification and IPC  
A61K9/20

Applicant  
TAKADA Kanji et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I    ☒ Basis of the opinion
  - II   ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV   ☐ Lack of unity of invention
  - V    ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI   ☐ Certain document cited
  - VII ☒ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.
 

**When?**    See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?**    By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:**    For an additional opportunity to submit amendments, see Rule 66.4.  
             For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
             For an informal communication with the examiner, see Rule 66.6.

**If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 27/03/2001.

Name and mailing address of the international preliminary examining authority:

European Patent Office

D-80298 Munich

Tel. +49 89 2399 - 0 Tx: 523656 epmu d

Fax: +49 89 2399 - 4465

Authorized officer / Examiner

**Hedegaard, A**

Formalities officer (incl. extension of time limits)

**Tantum, P**

Telephone No. +49 89 2399 8143



## WRITTEN OPINION

International application No. PCT/JP99/06602

### I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

#### Description, pages:

1-39 as originally filed

#### Claims, No.:

1-13 as originally filed

#### Drawings, sheets:

1/5-5/5 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

### V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

#### 1. Statement

Novelty (N)	Claims	1-13
Inventive step (IS)	Claims	1-13
Industrial applicability (IA)	Claims	

#### 2. Citations and explanations

see s parat sh t

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Re Section V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: US-A-4 765 983

D2: WO-A-98 24412

D1 discloses (see Fig. 1, col. 2, lines 58-68 and column 5, lines 64-68) an oral formulation comprising an adhesion site-controlling layer (3), a drug-carrying layer (2) containing a drug and a water-soluble polymer (e.g. an adhesive such as polyvinyl alcohol, sodium polyacrylate and methylcellulose) and a protecting layer (1), wherein the drug-carrying layer exists between the protecting layer and the adhesion site-controlling layer.

D2 discloses (see example 1) enteric coated particles, where the particles comprise a drug and a mucoadhesive and the enteric coating comprises e.g. Eudragit S100 or Eudragit L100. According to page 6, line 7 of D2 the particles can be placed into capsules.

Hence, the particle can be characterized as the drug-carrying layer, the enteric coating as the adhesion site-controlling layer and the capsule as the protecting layer (in accordance with present claim 1).

2. The subject-matter of claim 1 is not novel (Art. 33(2) PCT) over D1 and D2, each document taken separately (see above under item 1).
3. In any claims amended to overcome the novelty objection it will be necessary that said claims satisfy the requirements of inventive step (Art. 33(3) PCT). With regard to the assessment of inventive step in particular the document D2 appears relevant since concerned with oral formulations for gastrointestinal drug delivery.

4. A positive international preliminary report for the subject-matter of the dependent claims 2-13 can only be established when they refer to independent claims which meet the requirements of the PCT.

**Re Section VII**

**Certain defects in the international application**

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.





☐ EPA/EPO/OEB  
D-80298 München  
☎ +49 89 2399-0  
TX 523 656 epmu d  
FAX +49 89 2399-4465

Europäisches  
Patentamt

Generaldirektion 2

European  
Patent Office

Directorate General 2

Office européen  
des brevets

Direction Générale 2

## Correspondence with the EPO on PCT Chapter II demands

In order to ensure that your PCT Chapter II demand is dealt with as promptly as possible you are requested to use the enclosed self-adhesive labels with any correspondence relating to the demand sent to the Munich Office.

One of these labels should be affixed to a prominent place in the upper part of the letter or form etc. which you are filing.

## TENT COOPERATION TRE

PCT

NOTIFICATION OF RECEIPT OF  
RECORD COPY

(PCT Rule 24.2(a))

From the INTERNATIONAL BUREAU

To:

IMAMURA, Masazumi  
KRF Building  
5th Floor  
5-5, Kyobashi 1-chome  
Chuo-ku  
Tokyo 104-0031  
JAPON

00 2. 14 22

Date of mailing (day/month/year) 16 December 1999 (16.12.99)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 99355M	International application No. PCT/JP99/06602

The applicant is hereby notified that the International Bureau has received the record copy of the international application as detailed below.

Name(s) of the applicant(s) and State(s) for which they are applicants:

TAKADA, Kanji (all designated States)

International filing date : 26 November 1999 (26.11.99)  
Priority date(s) claimed : 27 November 1998 (27.11.98)  
21 September 1999 (21.09.99)

Date of receipt of the record copy  
by the International Bureau : 13 December 1999 (13.12.99)

List of designated Offices :

AP : GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW  
EA : AM, AZ, BY, KG, KZ, MD, RU, TJ, TM  
EP : AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE  
OA : BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG  
National : AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB,  
GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN,  
MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW


## ATTENTION

The applicant should carefully check the data appearing in this Notification. In case of any discrepancy between these data and the indications in the international application, the applicant should immediately inform the International Bureau.

In addition, the applicant's attention is drawn to the information contained in the Annex, relating to:

- ☒ time limits for entry into the national phase  
☒ confirmation of precautionary designations  
☒ requirements regarding priority documents

A copy of this Notification is being sent to the receiving Office and to the International Searching Authority.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer:  Masashi HONDA Telephone No. (41-22) 338.83.38
--	--

## PCT COOPERATION TREATY

PCT

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

From the INTERNATIONAL BUREAU

To:

IMAMURA, Masazumi  
KRF Building  
5th Floor  
5-5, Kyobashi 1-chome  
Chuo-ku  
Tokyo 104-0031  
JAPON

Date of mailing (day/month/year) 03 February 2000 (03.02.00)	
Applicant's or agent's file reference 99355M	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/JP99/06602	International filing date (day/month/year) 26 November 1999 (26.11.99)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 27 November 1998 (27.11.98)
Applicant TAKADA, Kanji	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An **asterisk(\*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
27 Nove 1998 (27.11.98)	10/353966	JP	28 Janu 2000 (28.01.00)
21 Sept 1999 (21.09.99)	11/266433	JP	21 Janu 2000 (21.01.00)

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. (41-22) 740.14.35</p>	<p>Authorized officer</p> <p>Taïeb Akremi</p> <p>Telephone No. (41-22) 338.83.38</p>
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## PATENT COOPERATION TREATY

PCT

NOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:  
IMAMURA, Masazumi  
KRF Building  
5th Floor  
5-5, Kyobashi 1-chome  
Chuo-ku  
Tokyo 104-0031  
JAPON



Date of mailing (day/month/year) 08 June 2000 (08.06.00)		
Applicant's or agent's file reference 99355M		IMPORTANT NOTICE
International application No. PCT/JP99/06602	International filing date (day/month/year) 26 November 1999 (26.11.99)	
Priority date (day/month/year) 27 November 1998 (27.11.98)		
Applicant TAKADA, Kanji		

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:  
AU,CN,JP,KR,MA,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:  
AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CR,CU,CZ,DE,DK,DM,EA,EE,EP,ES,FI,GB,GD,GE,  
GH,GM,HR,HU,ID,IL,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NO,NZ,OA,  
PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,TZ,UA,UG,UZ,VN,YU,ZA,ZW  
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).
3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on  
08 June 2000 (08.06.00) under No. WO 00/32172

**REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)**

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

**REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))**

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. (41-22) 740.14.35	Authorized officer J. Zahra Telephone No. (41-22) 338.83.38
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Continuation of Form PCT/IB/308

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF  
THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

<b>Date of mailing (day/month/year)</b> 08 June 2000 (08.06.00)	<b>IMPORTANT NOTICE</b>
<b>Applicant's or agent's file reference</b> 99355M	<b>International application No.</b> PCT/JP99/06602
<p>The applicant is hereby notified that, at the time of establishment of this Notice, the time limit under Rule 46.1 for making amendments under Article 19 has not yet expired and the International Bureau had received neither such amendments nor a declaration that the applicant does not wish to make amendments.</p>	

## PATENT COOPERATION TREATY

PCT

INFORMATION CONCERNING ELECTED  
OFFICES NOTIFIED OF THEIR ELECTION

(PCT Rule 61.3)

From the INTERNATIONAL BUREAU

To:

IMAMURA, Masazumi  
KRF Building  
5th Floor  
5-5, Kyobashi 1-chome  
Chuo-ku  
Tokyo 104-0031  
JAPON

RECEIVED

00. 6. 19 2000

SIKs &amp; C.

Date of mailing (day/month/year) 08 June 2000 (08.06.00)		
Applicant's or agent's file reference 99355M		IMPORTANT INFORMATION
International application No. PCT/JP99/06602	International filing date (day/month/year) 26 November 1999 (26.11.99)	
Priority date (day/month/year) 27 November 1998 (27.11.98)		
Applicant TAKADA, Kanji		

1. The applicant is hereby informed that the International Bureau has, according to Article 31(7), notified each of the following Offices of its election:

AP : GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW  
EP : AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE  
National : AU, BG, BR, CA, CN, CZ, DE, IL, JP, KR, MA, MN, NO, NZ, PL, RO, RU, SE, SK, US

2. The following Offices have waived the requirement for the notification of their election; the notification will be sent to them by the International Bureau only upon their request:

EA : AM, AZ, BY, KG, KZ, MD, RU, TJ, TM  
OA : BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG  
National : AE, AL, AM, AT, AZ, BA, BB, BY, CH, CR, CU, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IN, IS, KE, KG, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MW, MX, PT, SD, SG, SI, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW

3. The applicant is reminded that he must enter the "national phase" **before the expiration of 30 months from the priority date** before each of the Offices listed above. This must be done by paying the national fee(s) and furnishing, if prescribed, a translation of the international application (Article 39(1)(a)), as well as, where applicable, by furnishing a translation of any annexes of the international preliminary examination report (Article 36(3)(b) and Rule 74.1).

Some offices have fixed time limits expiring later than the above-mentioned time limit. For detailed information about the applicable time limits and the acts to be performed upon entry into the national phase before a particular Office, see Volume II of the PCT Applicant's Guide.

The entry into the European regional phase is postponed **until 31 months from the priority date** for all States designated for the purposes of obtaining a European patent.

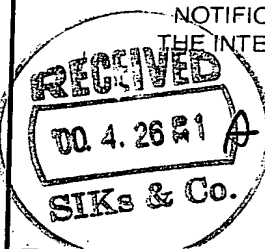
<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. (41-22) 740.14.35</p>	<p>Authorized officer: J. Zahra</p> <p>Telephone No. (41-22) 338.83.38</p>
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# TENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

# PCT

To:  
Imamura, Masazumi  
5th Floor, KRF Bldg., 5-5,  
Kyobashi 1-chome  
Chuo-ku, Tokyo 104-0031  
JAPAN



NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

11/04/2000

Applicant's or agent's file reference  
99355M

**FOR FURTHER ACTION** See paragraphs 1 and 4 below

International application No.  
PCT/JP 99/06602

International filing date  
(day/month/year)

26/11/1999

Applicant

TAKADA Kanji et al.

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Facsimile No.: (41-22) 740.14.35

**For more detailed instructions,** see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Barbara Klaver

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.



## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

**It must be in the language in which the international application is to be published.**

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>99355M</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/JP 99/ 06602</b>	International filing date (day/month/year) <b>26/11/1999</b>	(Earliest) Priority Date (day/month/year) <b>27/11/1998</b>
Applicant <b>TAKADA Kanji et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No.

JP 99/06602

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/20

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 4 765 983 A (TAKAYANAGI HITOSHI ET AL) 23 August 1988 (1988-08-23) column 1, line 6 - line 14  column 1, line 53 - line 57 column 2, line 68 - column 3, line 2 column 3, line 42 - line 49 column 4, line 32 - line 33; claims 1,6-8; figures 1,2; examples 1,2 ---	1-3,6,9  4,5,7,8, 10,11
X A	WO 98 24412 A (UNIV ILLINOIS ;GROVES MICHAEL (US)) 11 June 1998 (1998-06-11) page 1, line 2 - line 4 page 1, line 9 - line 18 page 4, line 8 - line 13 page 5, line 3 - line 9 page 6, line 6 - line 9; claims 1-4,8,9; example 1 ---	1,8,9,12  13
	--- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

4 April 2000

Date of mailing of the international search report

11/04/2000

Name and mailing address of the ISA

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Marttin, E

## INTERNATIONAL SEARCH REPORT

International Application No.

JP 99/06602

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 236 713 A (WATO TAKAHIKO ET AL) 17 August 1993 (1993-08-17) column 2, line 19 - line 28; figures 1-3 column 2, line 34 - line 47 column 3, line 33 - line 37; claims 1-4; example 3 -----	1-11

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

JP 99/06602

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4765983	A	23-08-1988	JP 1717687 C	14-12-1992
			JP 2060644 B	17-12-1990
			JP 61280423 A	11-12-1986
			DE 3618553 A	08-01-1987
			FR 2582942 A	12-12-1986
			GB 2177002 A,B	14-01-1987
-----				
WO 9824412	A	11-06-1998	NONE	
-----				
US 5236713	A	17-08-1993	JP 1110622 A	27-04-1989
			JP 2573969 B	22-01-1997
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## INTERNATIONAL SEARCH REPORT

International Application No

JP 99/06602

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 A61K9/20

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Minimum documentation searched (classification system followed by classification symbols)

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

4 April 2000

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Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

International Application No.

JP 99/06602

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

International Application No

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			GB 2177002 A, B	14-01-1987
WO 9824412	A	11-06-1998	NONE	
US 5236713	A	17-08-1993	JP 1110622 A	27-04-1989
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